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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,427	04/12/2004	Mark W. Kroll	A04P1032	4017

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PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER

HELLER, TAMMIE K

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/823,427

Applicant(s)

KROLL, MARK W.

Examiner

Tammie Heller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,8,10,11 and 13-22 is/are rejected.
- 7) ☒ Claim(s) 5-7,9 and 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed on November 4, 2005 has been received and considered. By this amendment, claims 1, 12 and 15 have been amended and claims 1-22 are pending in the application.

Specification

2. In view of the applicant's modification to the Specification, the Examiner is withdrawing the objection which was made against the specification in the last Office action.

Claim Objections

3. In view of applicant's modification to claim 12, the Examiner is withdrawing the objection which was made against claim 12 in the last Office action.

Response to Arguments

4. Applicant's arguments filed on November 4, 2005 have been fully considered but they are not persuasive.

Regarding the rejection of claims 1-3, 8, 10-11, 15-17 and 19-22 under 35 U.S.C. 102(a) based on the Fischell et al. patent, the applicant argues that the Fischell et al. reference does not disclose the use of a plurality of different electrode configurations to obtain a plurality of different cardiac activity signals to be used to discriminate between myocardial infarction and ischemia. However, as stated in the previous Office action, Fischell et al. discloses the use of a plurality of electrodes which are capable of providing a plurality of cardiac activity sensing electrode configurations (see paragraph 4 of previous Office action). Applicant's attention is also directed to column 1, lines 17-

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20, which states that the device of Fischell "could utilize as few as one lead or as many as three and each lead could have as few as one electrode or as many as eight electrodes". Furthermore, Fischell et al. discloses a sensing circuit which provides a plurality of electrograms based on the electrode configurations which are used. Applicant's attention is directed to column 15, lines 41-45, which specifies that the sensing amplifier 36 of Figure 4 is a "multi-channel amplifier" capable of amplifying a plurality of "electrogram signals 37" (plural). Digital to analog converter 41 would then convert these signals to "digital signals 38" (plural) prior to buffering them in FIFO memory 42. Finally, a discriminator 44 is disclosed which detects and discriminates between ischemia and myocardial infarction in response to ST segments of the electrograms produced by the sensing circuit (see paragraph 4 of previous Office action). The reference teaches that discrimination between ischemia and infarction is possible by correlating ST segment shifts with heart rate or R-R intervals (col. 2, ln. 19-21). Therefore, Examiner takes the position that the system of Fischell et al. discriminates between myocardial infarction and ischemia using a plurality of sensed cardiac activity signals obtained using the plurality of electrode configurations.

Regarding the rejection of claim 4 under 35 U.S.C. 103(a) as unpatentable over Fischell et al. in view of Steinhaus et al. (U.S. Patent No. 5,273,049), the applicant first argues that the rejection is moot based on the dependency of claim 4 from claim 1. However, based on the previously discussed rejection of claim 1, applicant's argument is not persuasive. Further, applicant argues that the summation taught by Steinhaus et al. is made with respect to samples taken from a single electrogram rather than more

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than one electrogram. Steinhaus et al. discloses that correlation analysis of ventricular electrograms is a technique for analyzing cardiac waveform morphology (see col. 3, ln. 15-17). Steinhaus et al. therefore discloses the use of more than one electrogram, through the use of the plural "electrograms", in the correlation analysis procedure. Therefore, applicant's argument that neither Steinhaus et al. nor Fischell et al. teach or suggest the invention as claimed in claim 4 is moot.

Regarding the rejection of claims 13-14 and 18 under 35 U.S.C. 103(a) as unpatentable over Fischell et al. in view of U.S. Patent Application Publication U.S. 2003/0023175, the applicant argues that the rejection is moot based on the dependency of claims 13-14 and 18 from independent claims 1 and 17. However, based on the previously discussed rejection of claims 1 and 17, applicant's argument is not persuasive.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 1-3, 8, 10-11, 15-17, and 19-22 are rejected under 35 U.S.C. 102(a) as being anticipated by Fischell et al. (U.S. Patent No. 6,609,023, cited by applicant). Regarding claims 1, 15-17, and 21, Fischell et al. discloses a system for the detection of cardiac events, including a plurality of electrodes which provide a plurality of cardiac

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activity sensing electrode configurations (see col. 15, ln. 28-32), a sensing circuit that provides a plurality of electrograms (see col. 34, ln. 19-21), and a discriminator 44 that detects and discriminates between ischemia and myocardial infarction in response to ST segments of the electrograms (see Figure 4 and col. 1, ln. 24-27).

Regarding claims 2 and 22, the discriminator 44 of Fischell et al. is disclosed to be responsive to positive ST segments of the electrograms with respect to a baseline in order to detect myocardial infarction (see Figure 6 and col. 20, ln. 55-58). Furthermore, Fischell et al. discloses a subroutine for ischemia detection that consists of setting an allowable factor increase or decrease, $\mu(A)$, in the ST shift detection and comparing this value to the detected ST shift (see Figure 10, step 485). Therefore, the discriminator of Fischell et al. is responsive to negative ST segments (an allowable factor decrease) of the electrograms with respect to a baseline to detect ischemia.

Regarding claim 3, the device of Fischell et al. is disclosed to include a conductive enclosure which is one of the plurality of electrodes (see col. 3, ln. 64-65).

Regarding claim 8, it is disclosed that the device of Fischell et al. discriminates between an ischemic condition, a myocardial infarcted condition, and an equivocal condition of the heart (see Abstract, ln. 23-25).

Regarding claims 10-11 and 19-20, Fischell et al. teaches that in response to detection of an equivocal condition, the discriminator provides a secondary analysis wherein the ST segment shifts are correlated with heart rate or R-R interval (see col. 2, ln. 19-21).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. in view of Steinhaus et al. (U.S. Patent No. 5,273,049). Fischell et al. discloses the invention essentially as claimed but fails to disclose a summer that provides a sum of the absolute value of the electrograms. Steinhaus et al. discloses a method for detection of cardiac arrhythmias using template matching which includes a normalization step wherein the normalize-electrogram-amplitude block 111 compensates for the variability in physiological signals by computing the sum of the absolute values of the electrogram signal samples (see Figure 5 and col. 14, ln. 7-9). The normalization step of Steinhaus et al. is utilized in order to compensate for the variability that is present in physiological signals and to improve the arrhythmia detection accuracy. Therefore, it would have been obvious to one of ordinary skill in the art to utilize the normalization step of Steinhaus et al. in the ischemia and myocardial infarction detection protocols of Fischell et al. in order to compensate for the variability present in physiological signals, thus improving the arrhythmia detection accuracy.

5. Claims 13-14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell et al. in view of Arzbaecher et al. (U.S. 2003/0023175). Fischell et al. discloses the invention essentially as claimed but fails to disclose the determination of

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an ischemia burden responsive to detecting ischemia. Arzbaeher et al. discloses an implantable cardiac arrest monitor system that detects ischemia and characterizes the severity of the risk based on the frequency and duration of the active ischemia, in order to evaluate the amount of damage to the heart tissue that may have been caused by the ischemic episode (see paragraph 44, ln. 12-13). Therefore, it would have been obvious to one of ordinary skill in the art to characterize the severity of the ischemic risk based on the duration of the ischemia, as taught by Arzbaeher et al., in order to evaluate the amount of damage to the heart tissue that may be caused by a given ischemic episode.

Allowable Subject Matter

6. Claims 5-7, 9, and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammie Heller whose telephone number is 571-272-1986. The examiner can normally be reached on Monday through Friday from 7am until 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766